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METHODS AND APPARTUS FOR BLOOD TYPING WITH OPTICAL BIO-DISCS

PROPOSED CLAIMS

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1. (Withdrawn) A method for determining a blood group type of an individual by direct typing on an optical bio-disc comprising:

applying red blood cells to at least one chamber in the optical bio-disc, the chamber surface including at least one capture field including a capture antibody, at least one positive control field, and at least one negative control field;

incubating the samples in the disc to promote antigen-antibody interaction;

placing the disc into an optical reader that supports it on a first side;

rotating the disc about an axis substantially perpendicular to the first side to separate non-captured cells from captured cells located on the chamber surface;

obtaining a measurement for the test field, the positive control field, and the negative control field

analyzing the measurement of the test field, the positive control field and the negative control field to determine blood group type of the individual.

2. (Withdrawn) A method for determining the presence of antibodies to an ABO blood group of an individual's blood sample by reverse-typing on an optical bio-disc including:

purifying serum from a blood sample;

creating at least one sample by mixing serum with cells of a known ABO blood group;

injecting at least one sample into at least one channel in the optical bio-disc, thereby delivering the sample onto a capture field including a cell binding molecule;

incubating the sample on the capture field to allow the agglutinated and non-agglutinated cells to bind to the cell binding molecule;

placing the disc into an optical reader that supports it on a first side;

rotating the disc about an axis substantially perpendicular to the first side;

scanning the chamber with an incident beam of electromagnetic radiation by rotating the disc about an axis substantially perpendicular to the first side by moving the incident beam in a direction radial to the axis;

detecting a return beam of electromagnetic radiation formed by at least a part of the incident beam after interacting with the disc;

converting the return beam into an output signal;

analyzing the output signal to determine the presence of cells bound on the capture field; and

determining the presence of antibodies in the sample.

3. (Withdrawn) A method for determining the presence of antibodies to an ABO blood group of an individual's blood sample by reverse-typing on an optical bio-disc comprising:

applying a blood sample to at least one microfluidic channel in the optical bio-disc including a separation chamber with at least one microfilter, at least one mixing chamber, and at least one capture chamber;

spinning for a first time the disc at a first speed to effect separation of the blood sample into cells and serum in the separation chamber;

spinning for a second time the disc at a second speed higher than the first, the second speed effecting movement of the serum through the microfluidic channel into a mixing chamber;

adding cells of a known ABO blood group cells into the mixing chamber containing serum;

spinning for a third time the disc in one direction and alternately in another direction at least once to effect mixing of the serum and the cells;

incubating the cells in the serum for a sufficient period of time to allow antibody-antigen binding;

spinning for a fourth time the disc at a third speed higher than the second, the third speed effecting movement of the cells into of a capture chamber, the capture chamber including surface with a molecule that binds cells;

incubating the sample in the capture chamber to promote cell binding to the chamber surface;

spinning the disc for a fifth time to remove non-bound cells from the capture field;

scanning the chamber with an incident beam of electromagnetic radiation by rotating the disc about an axis substantially perpendicular to the first side by moving the incident beam in a direction radial to the axis;

detecting a return beam of electromagnetic radiation formed by at least a part of the incident beam after interacting with the disc;

converting the return beam into an output signal;

analyzing the output signal to determine the presence of agglutinated cells; and determining the presence of antibodies in the sample.

4. (Withdrawn) A method for determining the presence of antibodies to a blood group type in an individual by antibody-typing on an optical bio-disc comprising:

purifying serum from a blood sample;

creating at least one sample by mixing serum with cells of a known blood group phenotype;

injecting at least one sample into at least one channel in the optical bio-disc, thereby delivering the sample onto a capture field including a cell binding molecule;

incubating the sample on the capture field to allow the cells to bind to the cell binding molecule;

placing the disc into an optical reader that supports it on a first side;

rotating the disc about an axis substantially perpendicular to the first side;

scanning the chamber with an incident beam of electromagnetic radiation by rotating the disc about an axis substantially perpendicular to the first side by moving the incident beam in a direction radial to the axis;

detecting a return beam of electromagnetic radiation formed by at least a part of the incident beam after interacting with the disc;

converting the return beam into an output signal;

analyzing the output signal to determine the presence of cells bound to the capture field; and

determining the presence of blood group antibodies.

5. (Withdrawn) A method for determining the presence of antibodies to a blood group type in an individual by reverse-typing on an optical bio-disc comprising:

applying a blood sample to at least one microfluidic channel in the optical bio-disc including a separation chamber with at least one microfilter, at least one mixing chamber, and at least one capture chamber;

spinning for a first time the disc at a first speed to effect separation of the blood sample into cells and serum in the separation chamber;

spinning for a second time the disc at a second speed higher than the first, the second speed effecting movement of the serum through the microfluidic channel into a mixing chamber;

adding cells of a known blood group cell phenotype into the mixing chamber containing serum;

spinning for a third time the disc in one direction and alternately in another direction at least once to effect mixing of the serum and the cells;

incubating the cells in the serum for a sufficient period of time to allow antibody-antigen binding;

spinning for a fourth time the disc at a third speed higher than the second, the third speed effecting movement of the cells into of a capture chamber, the capture chamber including a surface with an anti-human immunoglobulin molecule;

incubating the sample in the capture chamber to promote cell binding to the chamber surface;

spinning for a fifth time the disc to remove non-bound cells;

scanning the chamber with an incident beam of electromagnetic radiation by rotating the disc about an axis substantially perpendicular to the first side by moving the incident beam in a direction radial to the axis;

detecting a return beam of electromagnetic radiation formed by at least a part of the incident beam after interacting with the disc;

converting the return beam into an output signal;

analyzing the output signal to determine if the cells are agglutinated; and

determining the presence of blood group antibodies.

6. (Withdrawn) An apparatus for determining a blood group type of an individual comprising:

an optical bio-disc including at least one capture chamber including:

a layer including a first capture antibody, and

a layer including a second capture antibody bound by the first

capture antibody, the second capture antibody being specific for a blood group antigen;

a disc drive assembly;

an optical reader; and

software for blood group analysis.

7. (Currently amended) An optical-bio disc for performing a blood-typing assay, said disc configured to be rotated and said disc comprising:

a substrate;

a separation chamber in proximity to said substrate, said separation chamber including a first inlet port;

filter means in fluid connection with said separation chamber;

a first mixing chamber in direct fluid communication with said separation chamber so as to receive material communicated directly from the separation;

a second inlet port connected to the first mixing chamber and configured to communicate material received from a source other than the separation chamber to the first mixing chamber;

a second mixing chamber in direct fluid communication with said separation chamber, and not in direct fluid communication with said first mixing chamber so as to receive material communicated directly from the separation;

a third inlet port connected to the second mixing chamber and configured to communicate material received from a source other than the separation chamber to the second mixing chamber;

a first detection chamber in direct fluid communication with said first mixing chamber, said first detection chamber including a first capture ~~zone~~field; and

a second detection chamber in direct fluid communication with said second mixing chamber, said second detection chamber including a second capture ~~zone~~field; wherein the disc and chambers are configured such that fluid is transmitted from at least one of the chambers to another of the chambers that is in fluid communication therewith in response to rotation of the disc.

8. (Cancelled)

9. (Cancelled)

10. (Previously presented) An optical-bio disc as defined in Claim 7, wherein the separation chamber, the first and second mixing chambers and the first and second detection chambers are formed in the substrate.

11. (Previously presented) An optical-bio disc as defined in Claim 7, further comprising a cap that is bonded to the substrate.

12. (Previously presented) An optical-bio disc as defined in Claim 11, wherein the separation chamber, the first and second mixing chambers and the first and second detection chambers are formed in the cap.

13. (Previously presented) An optical-bio disc as defined in Claim 11 wherein the separation chamber, the first and second mixing chambers and the first and second detection chambers are partially formed in the cap and partially formed in the substrate such that the cap and substrate are bonded together in register to thereby fully form the chambers.

14. (Previously presented) An optical-bio disc as defined in Claim 11 further comprising a channel layer bonded between the cap and the substrate.

15. (Previously presented) An optical-bio disc as defined in Claim 14, wherein the separation chamber, the first and second mixing chamber and the first and second detection chambers are formed in the channel layer.

16. (Previously presented) An optical-bio disc as defined in Claim 7, further comprising an information layer which is configured to retain encoded information, said information layer located on the disc in a configuration such that the encoded information is readable by a disc drive.

17. (Previously presented) An optical-bio disc as defined in Claim 16, wherein the encoded information is used to define the manner in which the disc will be rotated.

18. (Previously presented) An optical-bio disc as defined in Claim 16, wherein the information layer is reflective.

19. (Previously presented) An optical-bio disc as defined in Claim 16, wherein the information layer is partially transmissive and partially reflective.

20. (Currently amended) An optical-bio disc for performing a blood-typing assay, said disc configured to be rotated and said disc comprising:

a substrate;

a separation chamber having components that are at least partially supported by the substrate;

a filter in fluid communication with the separation chamber;

a plurality of mixing chambers, each of which is separate from the other mixing chambers and each of which is in direct fluid communication with the separation chamber so as to receive material communicated directly from the separation chamber, and each of which includes an inlet port configured to communicate material into the mixing chamber from a source other than the separation chamber; and

a plurality of detection chambers, each of which is separate from the other detection chambers and each of which is in direct, fluid communication with one of the

mixing chambers; wherein the disc and chambers are configured such that fluid is transmitted from at least one of the chambers to another of the chambers that is in fluid communication therewith in response to rotation of the disc.

21. (Currently Amended) An optical-bio disc as defined in Claim 20, further comprising: a first inlet port connected to the separation chamber so as to communicate a blood sample into the separation chamber.; and

~~a plurality of second inlet ports, each of which is connected to one of the plurality of mixing chambers.~~

22. (Previously presented) An optical-bio disc as defined in Claim 20, wherein the separation chamber, the plurality of mixing chambers and the plurality of detection chambers are formed in the substrate.

23. (Previously presented) An optical-bio disc as defined in Claim 20, wherein each of the plurality of detection chambers further comprises a capture zone.

24. (Previously presented) An optical-bio disc as defined in Claim 20, further comprising a cap that is bonded to the substrate.

25. (Previously presented) An optical-bio disc as defined in Claim 24, wherein the separation chamber, the plurality of mixing chambers and the plurality of detection chambers are formed in the cap.

26. (Previously presented) An optical-bio disc as defined in Claim 24, wherein the separation chamber, the plurality of mixing chambers and the plurality of detection chambers are partially formed in the cap and partially formed in the substrate, such that the cap and substrate are bonded together in register to thereby form the chambers.

27. (Previously presented) An optical-bio disc as defined in Claim 24 further comprising a channel layer bonded between the cap and the substrate.

28. (Previously presented) An optical-bio disc as defined in Claim 27, wherein the separation chamber, the plurality of mixing chambers and the plurality of detection chambers are formed in the channel layer.